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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,705	09/07/2000	Magnus Bjorsne	3525-95	6406

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EXAMINER

ROBINSON, BINTA M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/623,705

Applicant(s)

BJORSNE ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

The examiner notes the applicant's election of Example 2 at paper no. 8.

The election of species will be used as a reference point for the examiner to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence and restriction will be required under 35 U.S.C. 121 and 372.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 3-20, drawn to the compound of formula I where A is a single bond, C1-6 is alkylene, -O(CH<sub>2</sub>)<sub>m</sub>-, m is 0-4, R<sub>4</sub> is H or C1-6 alkyl, R<sub>5a</sub>, R<sub>5b</sub>, R<sub>5d</sub>, R<sub>5e</sub>, R<sub>f</sub> are H or C1-3 alkyl, R<sub>2</sub> and R<sub>3</sub> are H, C1-4 alkyl (Optionally substituted with CN), OR<sub>7</sub> where R<sub>7</sub> is H, C1-6 alkyl or -(CH<sub>2</sub>)<sub>b</sub>-aryl where aryl is carbocyclic, b is 0-4, D is H, C1-4 alkyl, -OR<sub>9</sub>, where R<sub>9</sub> is H, C1-6 alkyl, X is O or S, and R<sub>1</sub> is C1-12 alkyl, a pharmaceutical composition, a method of treatment of an arrhythmia with a compound of formula I, and a process for the preparation of a compound of formula I.

Group II, claim(s) 1-20, drawn to the compound of formula I, a pharmaceutical composition, a method of treatment of an arrhythmia with a compound of formula I, and a process for the preparation of a compound of formula I.

Group III, claim 21 drawn to a compound of formula II

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Group IV, claim 22 drawn to a compound of formula IV

Group V, claim 23 drawn to a compound of formula VIII

Group VI, claim 24 drawn to a compound of formula XX

Group VII, claim 25 drawn to a compound of XXII

Group VIII, claim 26 drawn to a process for the preparation of a compound of formula VIII, XX, XXII or XXXV

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The species lack a common core.

By virtue of the applicant's election of species which falls into Group I genus, Group I will be examined. Claim 2 and the unelected portions of claims 1, 3-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant files a divisional application on the subject matter in group II or group VIII, the subject matter in groups II or VIII may be subject to further restriction.

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1. Applicant is advised that should claim 1 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

2. Applicant is advised that should claim 1 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

3. Claims 1 and 3-20 are objected to as being drawn to an improper Markush group on the grounds of lack of a common nucleus. The improper Markush group objection finds antecedent basis in case law. Compare *In re Swensen* 156 USPQ 180; *In re Ruzicka* 66 USPQ 226; *In re Winnek* 73 USPQ 225; *In re Harnish* 206 USPQ 300, 305 (CCPA 1980).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 11, 13, ~~14~~, 20 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A. In claim 20 in part, the term "derivative" is indefinite. It is unclear as to compounds are being claimed.

✓ B. In claims 13 and 14, the phrase "no effective amount of the compound to a patient in need thereof" is not included in these pharmaceutical claims. Pharmaceutical claims should include references to "an effective amount" of a compound being administered to a host in need thereof.

C. In claim 1, lines 4-6, page 72, and all other occurrences in claims 3-20, the phrase "(all of which are optionally substituted and/or terminated (as appropriate) by one or more substituents selected from OH, halo, cyano, nitro, C1-4 alkyl and/or C1-4 alkoxy)" is vague and ambiguous. How can R1 be terminated by more than one terminating group, if a terminating group, by definition, should terminate a radical? The phrase "(as appropriate)" in line 5, page 72 of claim 1 is also vague and ambiguous.

D. In claim 1, lines 22-23, page 74, and all other occurrences throughout claims 3-20, the phrase "(in which latter three groups" is indefinite. The phrase "A represents a single bond, C1-6 alkylene... -OH groups);" between lines 21-24 on page 74, should be rewritten in the form "A is \_\_\_\_, \_\_\_\_, or \_\_\_\_, or \_\_\_\_, \_\_\_\_, \_\_\_\_, and \_\_\_\_ which are optionally substituted with A and B, or \_\_\_\_ and \_\_\_\_ which are attached to the bispidine nitrogen..."

E. In claim 11, line 3, page 60, the phrase "in which latter two cases p is 1, 2, or 3)" is indefinite. The term "wherein" is suggested.

F. In claim 19, lines 3-4, page 61, the phrase "to a person suffering from, or susceptible to, such a condition" is indefinite. The phrase "to a patient in need thereof" is suggested.

G. In claims 17 and 18, line 1, the term "use" is indefinite because it is not statutory language.

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

<sup>3-13, 19-20</sup>  
Claims 1 and ~~3-20~~ are rejected under 35 U.S.C. 103(a) as being unpatentable

Lubisch et. al. . (See Reference N, EP 0308843).

Lubisch et. al. teaches the instant compound as shown in Formula I, where R is halogen, C1-C4 alkoxy, R1 is Halogen, C1-C4 alkoxy, Z is C1-C4 alkylene, R3 is H, C1-C4 alkyl, and R5 is C1-C4 alkyl. At page 5, rightmost column, lines 30-35, see formula I. The difference between the prior art compound and the instantly claimed compounds is the teaching of a generic compound versus a disclosed species. It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

8. The elected species appears to be allowable.

9. The IDS filed 2/20/2001 and 12/5/01 have been considered.

10. The EP 0308848 A2 reference cited as an X reference on the international search report appears to be an X reference

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta M. Robinson

*BMR*  
February 10, 2002

*Alan L. Rotman*

ALAN L. ROTMAN  
PRIMARY EXAMINER

*SPE A.U. 1625*